

We claim:

1. A method for treating an acute or chronic inflammatory disease which comprises administering
5 to a patient in need thereof therapeutically effective amounts of an IL-1 inhibitor and an additional anti-inflammatory drug, wherein said IL-1 inhibitor and at least one additional anti-inflammatory compound are administered separately or in combination.
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2. The method of claim 1 wherein the anti-inflammatory compound is methotrexate (N-[4-[(2,4-diamino-6-pteridiny]methylamino]benzoyl]-L-glutamic acid).
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3. The method of claim 1, wherein said IL-1 inhibitor is an IL-1 receptor antagonist.
4. The method of claim 3, wherein said IL-1
20 receptor antagonist comprises at least one compound selected from the group consisting of: IL-1ra α , IL-1ra β and IL-1rax.
5. The method of claim 4, wherein said IL-1ra
25 is human recombinant IL-1ra.
6. The method of any one of claims 1 through 5, wherein said inflammatory disease is an inflammatory disease of a joint.
- 30 7. The method of claim 6, wherein said inflammatory disease of a joint is rheumatoid arthritis.

8. The method of claim 2, wherein said IL-1 inhibitor and said methotrexate are administered in a pharmaceutically acceptable carrier.

5 9. A pharmaceutical composition comprising an IL-1 inhibitor and at least one additional anti-inflammatory compound.

10 10. The pharmaceutical composition of claim 9, wherein the anti-inflammatory compound is methotrexate (N-[4-[(2,4-diamino-6-pteridinyl)methylamino]benzoyl]-L glutamic acid).

15 11. The pharmaceutical composition of claim 9, wherein said IL-1 inhibitor is an IL-1 receptor antagonist.

20 12. The pharmaceutical composition of claim 11, wherein said IL-1 receptor antagonist comprises at least one compound from the group consisting of: IL-1ra α , IL-1ra β and IL-1rax.

25 13. The pharmaceutical composition of claim 12, wherein said IL-1 receptor antagonist is human recombinant IL-1ra.

30 14. The pharmaceutical composition of claim 13, wherein said human recombinant IL-1ra is present in an amount of up to about 200 mg.

 15. The pharmaceutical composition of claim 10, wherein said methotrexate is present in an amount of up to about 25 mg.

16. A use of an anti-inflammatory compound,
other than an IL-1 inhibitor, in the preparation of a
medicament for treating an acute or chronic disease in
a mammal in combination with the administration of an
5 IL-1 inhibitor.

17. The use of claim 16, wherein the anti-
inflammatory compound is methotrexate.

10 18. The use according to claim 17 wherein the
amount of methotrexate in the medicament is up to about
25 mg.

15 19. The use according to claims 16 through 18
wherein said methotrexate is administered orally.

20 20. A use of an IL-1 inhibitor in the
preparation of a medicament for treating an acute or
chronic inflammatory disease in a mammal in
20 combination with the administration of an additional
anti-inflammatory compound.

25 21. The use according to claim 20, wherein the
anti-inflammatory compound is methotrexate.

22. The use according to claim 20 wherein the
IL-1 inhibitor is an IL-1 receptor antagonist.

30 23. The use according to claim 22, wherein
said IL-1 receptor antagonist comprises at least one
compound selected from the group consisting of: IL-
1ra α , IL-1ra β and IL-1rax.

24. The use according to claim 23, wherein said IL-1 receptor antagonist is human recombinant IL-1ra.

5 25. The use according to claims 20 through 24 wherein the IL-1 inhibitor in the medicament is present in an amount of up to about 200 mg.

10 26. The use according to claims 21 through 25 wherein said methotrexate is administered orally.